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August 12, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004N-0264 –
Federal Measures to Mitigate BSE Risks: Considerations for Further Action

To Whom It May Concern:

This letter is in reference to Docket No. 2004N-0264, the agency's advance notice of proposed rulemaking (ANPR) and the invitation to comment on federal measures to mitigate BSE risks: Considerations for further action.

Valley Proteins, Inc. is one of the nation's largest non-captive recyclers of animal by-products and waste cooking oils with facilities located in 10 states. We process approximately 65 million pounds per week of these waste materials or about 7% of the total U.S. supply, and we provide service to over 40,000 meat and poultry processing plants, supermarkets, restaurants and farmers located in 17 states.

Before addressing the individual questions posed by the various agencies, we wish to first point out that animal by-products have been recycled into feed ingredients in the United States on a commercial basis for over 100 years. These recycled by-products were fed legally to ruminant animals throughout those 100 years until June 5, 1997 when the current feed rule was enacted by the FDA on June 5, 1997 with the full support of the U.S. Rendering Industry. We further wish to point out that it has been illegal to feed ruminant animals any ruminant based by-products including Specified Risk Materials (SRMs) for the past seven years, and that FDA's own inspection efforts in this regard indicate a compliance rate of over 99% by the rendering and feed industries. The underlining concept of the majority of these questions is whether SRMs should be removed from any or all animal feeds in the United States. The apparent reason for addressing SRM removal from feeds relates to two incidences of BSE in North America over the past 15 months. There has been no scientific evidence, only conjecture, to prove that either of these animals was ever fed prion infected animal by-products either legally prior to June 5, 1997 or illegally subsequent to that date. In fact, in order for these animals to have been exposed to BSE infectivity through animal feed, such disease would have had to exist in Canada in the first half of 1997 and prior. If this were the case, it is very difficult to believe that surveillance testing in both the U.S. and Canada would not have detected this disease much earlier than the year 2003.

USDA's International Review Team (IRT) formed in response to the U.S. BSE incident suggested a significantly increased surveillance effort to determine the underlining level of BSE within the U.S. cattle population. Starting June 1, 2004, USDA-APHIS commenced such a plan. We feel that based on the test results received thus far that no changes to June 5, 1997 feed rule are scientifically justified at this time. **We ask FDA and USDA to delay any contemplated changes to existing U.S. regulations in this regard until this enhanced BSE surveillance plan is completed proving whether BSE is in our cattle population or not and, if so, at what level.** The removal of SRM's and the significant cost burden on all members of animal agriculture cannot be justified unless there is a significant level of BSE in the U.S. cattle population.

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The following are our responses to each of the questions addressed by agencies:

2. What data or scientific information is available to evaluate the IRT recommendation described above, including that aspect of the recommendation concerning what portion of the intestines should be removed to prevent potentially infective material from entering the human food and animal feed chains?

There is no scientific basis for removing the brain, spinal cord, scull and vertebral column of cattle under the age of 30 months or more than the distal ileum from cattle over six months of age. While it is important to err on the side of caution, such regulations in this regard need to be based on the best scientific evidence available. BSE surveillance testing to date indicates virtually no BSE infectivity exists in the U.S. so removal of even the distal ileum does not appear warranted since rendered animal proteins containing this material cannot legally be fed to cattle and other ruminants. The cost of producing all meats in the United States will be increased substantially if these additional by-products are removed from the animal feed chains with only a slight reduction in risk exposure.

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm?
What information is available on the occurrence of on-farm feeding errors or cross contamination of ruminant feed with prohibited material?

Compared to Europe and the United Kingdom, in particular, animal agriculture in the United States is much more specialized. Nearly all poultry and swine in the United States are grown in confined facilities and fed concentrated diets specifically formulated for such species. Likewise, dairy farms are consolidating into much larger units which concentrate on this type of production and beef cattle production is likewise concentrating onto feedlots specializing in these animals. Therefore, the risk of cross contamination at the farm level is very small. This is further enhanced by the fact that feed cost for poultry and swine is much greater than that of cattle due to the much lower feed conversion rates for these species so there is no significant risk of cross contamination between poultry and swine feeds and ruminant feeds on farms in the United States. Since the compliance rate by the U.S. rendering and feed industries has been demonstrated through FDA inspections to exceed 99% and since U.S. BSE surveillance efforts indicate that this disease is virtually non-existent, there is no need to ban SRMs from all animal feeds.

4. If SRMs are prohibited from animal feed, should the list of SRMs be the same list as for human food? What information is available to support having two different lists?

There is no correlation between the need to ban SRMs from human food versus animal feeds. SRMs, which are rendered, have approximately a two-logarithm reduction in infectivity. Also, since June 5, 1997, it has been illegal to feed mammalian by-products to ruminant animals except for by-products derived from swine or equines. Finally, the head and spinal column contain approximately 90% of BSE infectivity so the removal of just these items significantly reduces risk in feed. Therefore, the risk of exposure to SRMs is completely different for humans versus livestock.

5. What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

There is no method currently available to conclusively verify through analytical testing whether a feed or feed ingredient contains SRMs. Even DNA testing cannot determine which part of an animal the tissue originated from.

6. If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM free rendered material and material rendered from SRMs?

If SRMs are prohibited from animal feed, these materials could be denatured by dyeing or with charcoal in order to mark them. Further, entities providing service for the removal and disposal of SRMs should be licensed to do business by the federal government or the applicable state department of agriculture. Their facilities should operate under federal and state oversight in a manner similar to facilities that process meat and poultry for human consumption. Each facility should be required to meet federal and/or state regulations before being licensed to handle SRMs and each should be required to maintain adequate detailed records to document where the SRMs are received from and the ultimate disposition of such material or the finished products derived from processing of such material. Since analytical tests cannot differentiate between SRM and non-SRM tissue, anything less than regulated disposal would provide for a "black market" for such SRM derived products.

7. What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?

At the present time, animal feeds are the highest and best use for animal fats and proteins derived from animal by-products. Currently, the value for tallow and meat and bone meal exceeds over $300.00 per finished ton or approximately $120.00 per ton on a raw basis. The value of these products when used as an energy source would range from $40.00 to $240.00 per ton on a dry basis and $16.00 to $96.00 per ton on a raw basis. This assumes that protein could be used as a coal substitute, but we have not investigated the capital cost nor environmental permitting requirements in order to use animal proteins as a source of solid boiler fuel. Until such time as a market can be developed to use animal proteins as a fuel, we could expect costs of between $40.00-$80.00 per finished ton or between $16.00-$32.00 on a raw ton basis for disposal in landfills. Approximately two-thirds of the yield of SRM material would be proteins so the lost market value and/or disposal cost per raw ton could equal from $88.00 to $152.00 on a raw ton basis versus the current values received from sales to feed manufacturers. As a result, animal processors would need to pay renderers millions of dollars annually to dispose of this material which they currently sell for millions of dollars each year.

There will also be an economic impact to the users of animal proteins. If 15-30% of the ruminant raw material is taken out of the feed supply, the price of SRM free MBM would obviously escalate, as would the price of other proteins derived from animals, poultry, fish and vegetables causing a significant economic impact on livestock and poultry producers.

Obviously, the environmental impacts would be significant since very little of this material presently goes into our nation's landfills. Of more concern would be if SRM material was disposed of in landfills prior to processing. This material contains a significantly greater biological load than materials normally deposited in the landfills. Since the rendering process deactivates virtually all this biological activity, it would be important that this material continue to be rendered in order to 1) reduce its volume by approximately 65% and 2) deactivate such biological activity.

8. What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

There should be no significant concerns relating to human exposure to SRMs through contact with or ingestion of animal feed or pet food. Animal feeds and pet foods are both packaged in manners where it is obvious that they are not intended for human consumption. The risk of using these products with SRMs included is no greater than the risks assumed when handling these products, or any other product, which is not packaged under food safety inspection oversight. In fact, with the level of BSE in Europe and the United Kingdom, specifically, if this were a problem it is likely that it would have been detected there by this point.

9. What information, especially scientific data, is available to show that dedicated

facilities, equipment, storage, and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation? If so, what would be the scientific basis for such a prohibition?

The United States' BSE Surveillance testing shows that there is virtually no BSE infectivity in the U.S. cattle population. Therefore, the small amount of protein, which remains in production and transportation equipment in the form of residues, would not likely be great enough to cause concern regarding cross contamination in animal feeds. Further, over the past seven years since the introduction of the June 5, 1997 feed rule, virtually all facilities in the United States, both rendering and feed manufacturing, have specialized in either materials which can be fed to ruminant animals or those that cannot. There is a much lower likelihood today than ever before of cross contamination within these facilities. Similar to livestock and poultry production, rendering and feed facilities have become largely specialized in handling by-products of specific species and for providing products to feed specific species.

FDA's inspections of these facilities over the past several years should provide adequate evidence that SRMs have not been and, in the future, will not be fed to ruminant animals.

10. What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage, and transportation?

The majority of rendering and feed facilities have already been dedicated to ruminant and non-ruminant species, so there is very little batching and flushing at these facilities currently. However, from a transportation standpoint, trucks and train cars do move products of different types. Since most poultry is grown in one sector of the country while most ruminants are grown in another, it is very important that trucks and train cars be allowed to load ruminant based rendered products destined for poultry in one direction and poultry based rendered products destined for ruminants on the return trip. This efficient use of transportation equipment will continue to facilitate that the correct animal proteins are utilized in the proper feeds. Should dedicated facilities be required by FDA, there needs to be established procedures for reassigning facilities and equipment which have been dedicated to SRMs and other prohibited materials to use for feed-bound products.

From an environmental point of view, any increased costs for handling SRMs will cause more of this material to be disposed of in our nation's landfills instead of through rendering which will result in increased environmental exposure due to the high biological load of this material in its unprocessed state. There is also a high likelihood of significantly increased illegal disposal of dead animals on farms and in the surrounding communities as well as the loss of the availability of these animals from the Country's BSE surveillance efforts.

11. What information, especially scientific data, is available to demonstrate that cleanout would provide adequate protection against cross contamination if SRMs are excluded from all animal feed?

On-going surveillance testing for BSE in the United States shows that this disease is virtually non-existent in our livestock population. Therefore, SRMs in the United States likely do not contain significant doses of prion infectivity. Also, the FDA's own inspections of rendering plants and feed mills indicate a compliance rate of over 99% with the feed rule enacted on June 5, 1997 which demonstrates that our current regulations are working quite well. As a result, small residual cross contamination which would be left after a normal clean out procedure is unlikely to have a significant impact on U.S. animal health. The FDA might consider regulating procedures where a shipment of product destined for a non-ruminant species must be transported after rendered animal proteins derived from SRMs are hauled by the same vehicle before such vehicle could again be used to transport any materials destined for ruminant feeds.

12. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

In the United States less than five percent of the feed that is fed to poultry and swine is derived from animal proteins. Therefore the volume of undigested feed when an animal is slaughtered for human consumption is very minuscule, particularly, after this material has been rendered. Since U.S. BSE surveillance testing shows there is virtually no BSE in our cattle population, the volume of potentially infected material which could pass through rendering channels would not likely be sufficient to cause a problem in ruminant animals. Further, both the United Kingdom and much of the rest of Europe fed significant volumes of contaminated animal proteins to swine and poultry in the 1980's and 1990's with no scientific evidence that these by-products caused similar disease issues in these species.

13. If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

There is no scientific data supporting the need for removal of all mammalian and avian MBM from ruminant feed. Certainly, if FDA prohibits SRMs from all feeds, there would be no reason whatsoever to remove mammalian and avian MBM from ruminant feed. Also, if FDA prohibits SRMs from all animal feeds, it may not be necessary to continue the June 5, 1997 feed rule, since it may be determined that ruminant by-products exclusive of SRMs could be safely fed to ruminants.

14. What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

Ruminant feed currently makes up approximately 20% of the market for U.S. animal proteins. The loss of this market would most likely reduce the value of animal proteins in the United States by nearly 30% when compared to those of competing ingredients such as soybean meal. An economic study would be necessary to determine the extent of this impact.

Again, the environmental impact would be significantly greater than current because of the increased cost for the disposal of this material would likely encourage many producers to landfill this material instead of disposing of it through rendering.

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

There is no scientific evidence to support that the use of bovine blood or blood products in feed poses a risk for BSE transmission in cattle and other ruminants. Also, the elimination of ruminant blood meal reduces the supply of blood meal to ruminant animals by over 60% which will significantly increase the cost of feeding such animals and result in higher prices particularly for dairy products.

16. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

There is no scientific data or other information to show that plate waste poses any risk for BSE transmission in cattle and other ruminants since this material has been previously prepared for human consumption. Further, since early 2004, SRMs have been removed from human food in the United States which virtually eliminates the risk of feeding these products.

17. If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

There is no scientific evidence for banning SRMs from animal feeds other than for ruminants. However, should FDA prohibit SRMs from all animal feeds, there could be no possible need to prohibit the use of

poultry litter in ruminant feed since SRMs would not be used as a poultry feed and therefore, no potentially prion infected material would be in either the spilled feed or the feces of avians.

18. What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

There is no scientific evidence for banning these products from ruminant feed. However, should FDA prohibit them from ruminant feed, there will be a reduced market for such products which will ultimately lower their market value. As the value for these products is reduced, their disposal costs will increase providing an economic incentive to disposing of them in other, and many times illegal, fashions. These products would likely be disposed of in either landfills or by land application on farms. Poultry litter in particular may be applied to farmland at a greater concentration causing more run-offs into the nation's water bodies and could create additional water pollution impacting both environmental and human health.

19. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, dead stock, and non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

There is no scientific evidence showing any risk of BSE transmission from rendered animal fats and tallows. The 0.15% standard was set by the OIE and is used for trading these even products in countries with significant levels of BSE in their cattle populations. Further, should FDA regulate fat products based on this standard, the insoluble impurities content needs to be determined by the AOCS method which is the commonly accepted testing method throughout the United States.

20. Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

There is no scientific basis for excluding the entire carcass from dead stock and non-ambulatory disabled cattle from all animal feeds. However, while in many cases it would not be economically feasible to remove SRMs from these carcasses, should FDA ban SRMs from all animal feeds and should there become a market of great enough value to allow SRMs to be economically removed from such animals, renderers and others should have that option.

2 1. What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?

We know of no analytical test which can be used to verify whether a feed ingredient includes the by-products from one part of a bovine versus another or from a healthy animal versus a diseased or dead animal.

22. What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

Presently, the cost of collecting and disposing of dead stock and non-ambulatory disabled cattle is partially reimbursed by the value of the finished animal fats and proteins derived from the processing of such animals. If these animals were prohibited from use in animal feed, there would likely be a resulting decline in value of $88.00 to $152.00 per raw ton for this material. This reduced incentive for farmers to dispose of animals via rendering would increase their incentive to either land fill or illegally dispose of these carcasses and would add to animal disease and pollution problems which already exist in our country.

26. How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training?

No comment.

27. How can the Federal Government increase access to these materials?

No Comment

28. Should FDA include exemptions to any new requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants?

Yes. Since much is not known about prion diseases, or the manner in which they spread, it would be very desirable to have a standing committee that would meet regularly to address these issues and the need to modify federal regulations in this regard. This disease was first discovered nearly 19 years ago and over the years many issues which were thought to play a part in the disease have since been proven to be of no effect, including 1) that the disease originated from scrapie in sheep and 2) that changes in rendering processes in the United Kingdom resulted in reduced deactivation of BSE. In the future, we may find that other activities were falsely believed to control the spread of this disease and are no longer necessary.

29. If so, what process should FDA use to determine that the technologies or test methods are practical for use by the feed industry and ruminant feeders and provide scientifically valid and reliable results?

The FDA should assist industry with research grant funds for projects to be performed by accredited colleges and universities or government research agencies which help determine how products produced by these industries can be safely used as feed ingredients either for ruminant or non-ruminant animals.

30. Do FDA's existing authorities under the Federal Food, Drug, and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRMs and other cattle material in non ruminant animal feed (e.g., feed for horses, pigs, poultry, etc.) notwithstanding that such materials have not been shown to pose a direct risk to non ruminant animals? More specifically, under FDA's existing legal authorities, would the potential occurrence of on-farm feeding errors, of cross contamination of ruminant feed with SRMs and other cattle material, or of human exposure to non ruminant feed (including pet food) provide a basis to ban SRMs and other cattle material from all animal feed?

No comment. This is an item that would need to be researched by legal counsel.

31. Are there other, related legal issues on which FDA should focus?

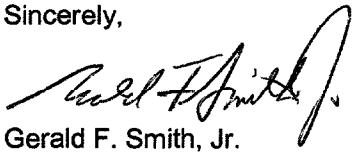
No comment.

In closing, we wish to thank the Agency for the opportunity to provide comments in this regard and for the responsible manner in which the agencies have dealt with the recent BSE incident in the United States. We believe that these efforts have provided adequate and reassuring information to the U.S. consumer and to our overseas trading partners. We, however, encourage the agencies to delay any further regulations until we have a clearer picture of whether or not we have BSE in the United States and at what level, and we are certain the agencies can comfortably wait for these results since we have an excellent program for keeping potentially prion infected by-products from our ruminant animals.

Re: ***Federal Measures to Mitigate BSE Risks: Considerations for Further Action***
Docket No. 2004N-0264

On behalf of our over 1,300 employees and 40,000 by-products suppliers we thank you for this opportunity to comment on the ANPR.

Sincerely,



Gerald F. Smith, Jr.
President

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